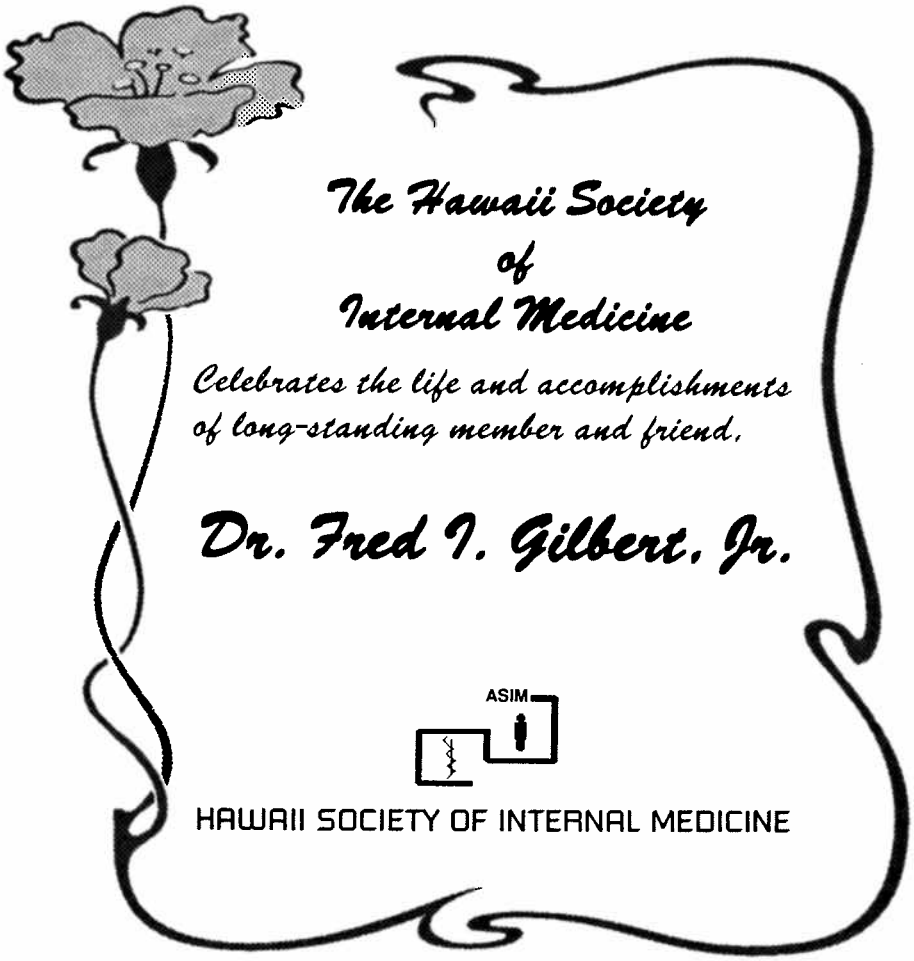
arguing that the aim is elimination of hyperthyroidism, that larger doses accomplish it with more certainty, and that the inevitable hypothyroidism develops under physician control. This approach raises a new question: In the tradeoff between curing hyperthyroidism and the radiation risk, how much ^{131}I is enough? To answer this, we examined the proportion cured (proportion of hyperthyroidism eliminated) for 605 patients with Graves' disease treated at progressively increasing fixed doses of ^{131}I.

Large prospective studies. *Expensive long-term, randomized, double-blind, crossover studies are essential to settle some important questions, and Dr Gilbert's teams have been involved in a number of federally funded ones. The Coronary Drug Project eliminated Atromid-S and D-thyroxine as cholesterol-lowering agents because they did more harm than good; the Systolic Hypertension in the Elderly Project determined that treatment of persons with this condition improved life expectancy. This broader approach to clinical research is exemplified by the Breast Cancer Detection Demonstration Project (BCDDP). To execute the 10-year venture successfully required innovative uses of highly trained non-physician personnel, constant quality monitoring, a high level of team coordination, and a lookout for improved technology and new ideas. Among the national centers, Dr Gilbert's was the first to insist on using rare-earth radiologic screens which reduced radiation by 90%; this gradually spread throughout the U.S. At the end of the project he gave mammographic instruments to three hospitals that agreed to carry out low-cost screening for women of Hawaii.*



What Have We Learned from the Breast Cancer Detection Demonstration Project?

Fred I. Gilbert, Jr, MD, Gloria Low MPH

Reprinted from the *Hawaii Med J.* 1986;45:279-292.

Between 1974 and 1979, 10,000 women with no symptoms or suspicion of breast cancer entered a screening project to detect the presence of breast cancer in asymptomatic women. Of the 10,000 women, 181 breast cancers were discovered in 171 women during the five-year screening period. An additional 82 women developed 89 breast cancers during the five-year follow-up period.

Although preliminary analysis of this data has been published both nationally and locally,[2-3] this article summarizes what we have learned from this project over the past decade and some of the unresolved issues. A similar report has been distributed via a final newsletter to the 10,000 women who participated.

The Breast Cancer Detection Demonstration Projects (BCDDP) raised the level of capability of early detection of breast cancer in Hawaii and the nation. It was started here in Hawaii early in 1974.

Accomplishments

For years we knew that some women were lucky enough to have had a minute breast cancer discovered and treated because it happened to be next to or in a biopsied lump. In the early 1970s, the Breast Cancer Detection Demonstration Projects brought to communities across the country the means to detect systematically these tiny, often microscopic, cancers through the use of the relatively new technique of breast x-ray imaging called mammography. Initially, personal physicians, surgeons, radiologists, and pathologists had difficulty in making decisions about suspected cancers that neither could be seen nor felt. However, increased use of mammographic units and technical improvements were paralleled by increased professional skills in both the diagnosis and management of breast cancer. Diagnosing smaller localized cancers resulted in more conservative forms of treatment that offered an alternative to radical mastectomy. This new knowledge was made available to women, enabling them to participate more actively in decisions regarding treatment.

In 1975, the Kodak Company developed the rare-earth screen that converts x-ray energy into light energy. The author (Gilbert) applied this to mammography in Hawaii's BCDDP the same year. This new technique resulted

in an enormous reduction in radiation exposure without losing definition. These screens not only reduced mammographic radiation to 10% of what had been a previous low level, but also led to similar reductions in radiation levels in other procedures, such as x-rays of the chest.

While physicians improved their skills, nurses and x-ray technologists were trained and learned how to palpate the breast for possible tumors. This new skill was honed to a very high degree because these people received precise instruction on breast examination and then performed 20 or more examinations daily, month after month.

Utilizing these improved capabilities during the five years of screening, the BCDDP detected 181 breast cancers in women who were unaware that they had it. Although almost 45% of these cancers could be felt with the fingertips, an additional 42% were so small that they could be detected only by mammography. In any screening program, the first screening yields the largest number of cancers: 55 women of the 10,000 in the Hawaii project were found to have breast cancer during the first screening round (which took two years) and 41 during the second round. An average of 30 women were diagnosed annually thereafter, bringing the total to 181.

There is no question that mammography is a screening technique that can save lives. In these women, diagnosed with very early breast cancer, the five-year survival rate is 96%. This is very much better than the five-year survival rate of 71% in women with larger cancers and cancers that have spread to the lymph nodes.

False Negatives and False Positives

Screening techniques still are not perfect. Even with the best available skills and technology, and screening as frequently as every year, 13% of these 181 cancers were undetectable at screening but became evident within a year. At the same time, a high percentage of breast biopsies or aspirations, done as a consequence of the screening, turned out to be negative for cancer. Therefore, some women who ultimately are proven to be free of breast cancer may, because of suspicious findings on palpation or mammography, undergo emotional stress and the expense of biopsy, only to discover that the abnormal finding is not a cancer. On the other hand, a normal mammogram or a negative aspiration or biopsy may greatly allay fears about the presence of breast cancer.

Screening Intervals

The question of what is the appropriate interval between mammographic examinations still needs further evaluation. Recent studies in the Netherlands have shown an improved five-year survival rate, when screening mammograms were done 18 to 24 months apart. Of course, more cases could be diagnosed at an earlier stage if screening were done as often as every 12 months, but, so far, a 12-month interval between examinations has not been accepted by the majority of physicians or by women. Ten out of 11 women feel that x-ray examinations are probably too hazardous and too expensive to be worth the potential benefit. How often to have screening mammograms will depend on individual circumstances and the willingness of both individuals and society to pay for such examinations.

The true cost of a set of screening mammograms, under optimal conditions, is close to $50. However, the chances of finding a cancer in women at random risk are only about two out of 1,000. It ends up costing society approximately $25,000 per discovered breast cancer in women who have no signs or symptoms! This figure includes, in addition to screening mammograms, costs such as biopsies for false positives, extra office visits, and so forth, which amount to an average of about 10 times the initial mass screening cost. Obviously, we still need better ways to identify women at increased risk, and we need better and less expensive ways of detecting breast cancer, especially early and potentially curable breast cancer. Most of all, we need to know how to *prevent* breast cancer, which is only a faint hope at present.

What Can a Woman Do?

Until we can answer precisely the question of prevention, women can, for now, reduce the risk of breast cancer by following a general guideline for good health. Substances that are known to have detrimental effects on general health should be avoided. For example, it is known that fat women and women

who eat a high-fat diet are more apt to develop breast cancer. This suggests that a balanced diet without excessive calories, particularly as fats and oils, may not only benefit total well-being but also result in lowering the risk for breast cancer. Regular exercise and recreation contribute to weight control by burning up calories and providing a means of managing stress. Ineffectual management of stress does lead to overeating.

Affordability of Screening Mammography

The cost of mass screening for breast cancer is, in our opinion, still too high. As stated above, the actual cost of taking and interpreting a set of screening mammograms under nearly optimal conditions is about $50. By contrast, the cost of diagnostic mammography (when there is a suspicion of cancer) is about twice as much as screening mammography, but is often covered in part by insurance plans. The answer to high cost is neither government subsidy nor insurance coverage. Either course would merely shift costs, rather than reduce them.

Several factors influence the cost and hence the affordability of screening examinations for breast cancer. First and foremost, the cost of the test itself: Not only is the mammography equipment expensive ($70,000 or so), but so are the necessary services of highly trained personnel. Additionally, there are the expenses involved in following up suspicious findings, which often prove to be benign. Second, the frequency of screening: Annual screening can be more than a lot of women can afford. Finally, the site: The track record suggests that low-cost screening services are more likely to be available in a nonhospital setting or a facility that is specially set up for such services, utilizing volunteer help and other community support mechanisms, rather than a hospital or a private radiological laboratory.

Another factor to be considered is that the lack of any effective method of identifying women at high risk means that all women must be considered as at risk. Although there is a relatively high probability of a woman developing breast cancer during her lifetime (one in 11), there is a relatively low probability of her developing it in any one year (one in 400). Therefore, the ideal screening test for a disease such as this one would have to be very inexpensive so that it can be utilized repeatedly by all women over age 40. Unfortunately, such a test is not yet available. However, using the tests we do have, the BCDDP has demonstrated several cost-effective techniques of screening that reduce costs and increase quality at the same time.

The BCDDP has shown that trained, non-physician examiners can perform screening breast examinations very well. Specially trained technologists can distinguish normal mammograms from abnormal ones, thus permitting the radiologist to focus his attention on the abnormal ones. Women appreciate the opportunity that is also provided, to learn breast self-examination on their own bodies. Palpation and mammographic examinations of good quality require proper training, proper maintenance of the mammographic unit and monitoring of radiation, proper positioning of the screenee and processing of film, interpretation of films, and followup of suspicious findings. Moreover, the quality of the procedure depends heavily on the number of exams performed daily. Thus, a facility that keeps its acumen finely honed by a large volume of cases would be the place to have a screening done.

Although research will proceed on the question of optimal frequency and other issues, we feel that screening mammography should be offered to the public, while efforts to lower cost and improve efficiency continue.

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